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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,858	12/18/2001	Graham Stanley Leonard	P31220X2C2	1864

20462 7590 09/24/2002

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/24/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,858

Applicant(s)

LEONARD ET AL.

Examiner

Humera N Sheikh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2002 (paper no.5).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-19 and 22-24 is/are allowed.
- 6) ☒ Claim(s) 9-13, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/817,911.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the IDS and the preliminary amendments, all filed 12/18/01 and the IDS filed 03/20/02.

Claims 9-24 are pending. Claims 9-13 and 20-21 are rejected. Claims 14-19 and 22-24 are allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-13 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (WO 92/09281).

Johnson disclose an oral administration pharmaceutical composition for use in the treatment of bulimia and anorexia, comprising an effective amount of a selective serotonin reuptake inhibitor (SSRI) – paroxetine or a pharmaceutically acceptable salt

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thereof, wherein the preparation can be designated in the form of slow release or enteric coated tablets (see reference page 1, lines 17-36 through page 3, lines 1-25) and (claims 16,18 and 19).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-13 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (WO 92/09281).

Johnson teach an oral administration pharmaceutical composition for use in the treatment of bulimia and anorexia, comprising an effective amount of a selective

serotonin reuptake inhibitor (SSRI) – paroxetine or a pharmaceutically acceptable salt thereof, wherein the preparation can be designated in the form of slow release or enteric coated tablets (see reference page 1, lines 17-36 through page 3, lines 1-25) and (claims 16,18 and 19). Examples of pharmaceutically acceptable salts of paroxetine are paroxetine hydrochloride, p. hydrobromide, p. acetate and p. maleate. Johnson teach that the paroxetine preparation may be formulated for administration by any route, such as the oral route and can be in the form of tablets, capsules, lozenges, etc. (page 2, lines 29-32). The tablets may be coated (i.e., enteric coated tablets) according to methods well known in the pharmaceutical practice or may, if desired, be designed to give slow release of paroxetine (page 2, lines 23 through page 3, line25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the pharmaceutical medicament of Johnson who teaches the selective serotonin reuptake inhibitor, paroxetine, in a delayed release formulation because it has now been discovered that paroxetine has potential therapeutic utility for treating bulimia and anorexia. The expected result would be an effective, enterically coated tablet for the treatment of bulimia and anorexia and hence and effective treatment for vomiting.

Allowable Subject Matter

Claims 14-19 and 22-24 are allowed.

Prior art made of record and deemed relevant by the examiner:

WO 95/15155 Francese et al. (06-1995)

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600